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☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).

Notice of Draftperson's Patent Drawing Review, PTO-948
Notice of Informal Patent Application, PTO-152

Interview Summary, PTO-413

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11/8/2/01 DATE MAILED: This is a communication from the examiner in charge of your application COMMISSIONER OF PATENTS AND TRADEMARKS **OFFICE ACTION SUMMARY** Responsive to communication(s) filed or ☐ This action is FINAL. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 D.C. 11; 453 O.G. 213. A shortened statutory period for response to this action is set to expire month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). **Disposition of Claims** is/are pending in the application. is/are withdrawn from consideration. Claim(s) is/are allowed. Claim(s) is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction or election requirement. **Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on is/are objected to by the Examiner. The proposed drawing correction, filed on \_ \_is 
\_\_ approved 
\_\_ disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) received in this national stage application from the International Bureau (PCT Rule 17.2(a)). \*Certified copies not received: Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) ☐ Notice of Reference Cited, PTO-892

Serial No. 08/982272 Art Unit 1644

## **DETAILED ACTION**

- Applicant's amendment, filed 8/20/01 (Paper No. 23), has been entered. Claims 1-10, 67 and 83-86 have been canceled. Claims 87-136 have been added.
- 2. Newly submitted claims 87-136 are directed to a number of species that are independent or distinct from the invention originally claimed and elected for the following reasons:

Newly submitted claims are drawn to methods of expressing CD40L or increasing the concentration of CD40L in cells by transfecting chimeric CD40L molecules which comprise both murine and human CD40L as well as CD40L and TNF-alpha, TNF-beta, Fas ligand, CD70, CD30 ligand, 4-1BBL, Nerve growth factor beta and TRAIL, previously not elected and/or not claimed. The newly submitted claims are drawn to transfected chimeric molecules which differ in structure and function and which are distinct from the originally elected invention of methods which relied upon transfecting CD40L alone.

Therefore, claims 91-98, 103-110 have been withdrawn from consideration.

As indicated previously, claims 11-66, 68-82 and the non-elected species have been withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to the nonelected inventions.

In addition, applicant has presented new claims which encompass distinct species previously not claimed and are subject to species election.

- 3. This application contains claims directed to the following patentably distinct species of the originally present invention of Group 1: wherein the CD40L specificity is:
  - A) murine CD40L or
  - B) human CD40L.

These species are distinct because their structures, interactions, modes of action are different.

## Serial No. 08/982272 Art Unit 1644

In addition, this application contains claims directed to the following patentably distinct species of the originally present invention of Group 1: wherein the cell is:

- A) neoplastic B cell,
- B) CLL cell,
- C) neoplastic T cell,
- D) neoplastic dendritic cell,
- E) neoplastic monocyte cell,
- F) neoplastic myelomonocyte cell,
- G) breast tumor cell,
- H) ovarian tumor cell,
- 1) lung tumor cell, or
- J) cell derived from connective tissue surrounding neoplastic cells.

Also, if applicant intends to include non-neoplastic cells, such as B cell, and dendritic cells, then these normal cells would also be subject to species election.

These species are distinct because their structures, interactions, modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

4. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Serial No. 08/982272 Art Unit 1644

- 6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
- 7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
November 1, 2001